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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,739

08/21/2003

Shaher A. Ahmad

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SUITE 600

DALLAS, TX 75201-2980

EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

NOTIFICATION DATE

DELIVERY MODE

04/21/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/645,739	Applicant(s) AHMAD, SHAHER A.	
	Examiner JAMES L. SWIGER	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-51 is/are pending in the application.
- 4a) Of the above claim(s) 17-29 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-16, 30-32 and 36-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/21/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14-16 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. (US Patent 5,417,692).

Goble et al. disclose a driver (23) having a tip portion and a driver edge and an external surface (see Fig. 3), wherein the tip portion has a plurality of inner surfaces to match the hexagonal shape, and also wherein the bottom portion of the tip (the tapered bottom portion of 23) forms a rim outside of a second portion, which may be considered 15 (also an insert) that is capable of being inserted into the threaded bore of the bone screw portion, and wherein the rim interfaces with the shoulder of the bone anchor portion so it may be used to aid the bone anchor insertion into bone. This also has a distance that is approximately equal to the distance between the shoulder of the bone anchor and the end of the protrusion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 30, 32, 36, 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. '692 in view of Kwan (US Patent 5,338,197).

Goble et al. disclose a bone anchoring device comprising a screw portion (37) that penetrates bones, having a retention thread (39) on at least part of the screw portion, and a tip (40), a protrusion (44) that is considered at least to have a shoulder portion (18) in combination with the protrusion (see also Fig. 9) that is adjacent the second end of the screw portion, opposite the tip, with a plurality of sides in a hexagonal shape (see Fig. 4a). Goble et al. also disclose a protrusion with a hollow interior portion (19) with threads (see Fig. 10) configured to retain a component therein, and also wherein the protrusion has a maximum width that is smaller than the maximum diameter of the screw portion such that it is able to form a shoulder (see again Fig. 10). The screw portion also has a conical shape and has flutes (considered as the threads, which may cut the bone as it is inserted). They are also considered 180 degrees apart, if considered in opposing sides).

Goble et al. disclose the claimed invention except for the rounded interior surface having a single, continuous thread along at least a majority of the length of the bone screw. Kwan discloses a bone anchor with threads along a majority of an interior surface (60) which helps with installing the anchor pin when being inserted into bone

(See also Col. 5, lines 33-57). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone anchor of Goble et al. having at least continuous threads in a recess in view of Kwan to have better control and orientation when installing the anchor.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Goble et al. '692 and Kwan '197. Goble et al. disclose the claimed invention except for the bone anchor shape coming in a variety of shapes. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the bone anchor having a variety of shapes to match the shape of the driver tool, since applicant has not disclosed that such a modification may solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of inserting a bone anchor using a driver tool. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Goble et al. '692 and Kwan '197 and in further view of Kay (US Patent 5,662,683). The combination of Goble et al. '692 and Kwan '197Goble et al. disclose the claimed invention except for a bone anchor having a length that is approximately 0.20 inches. Kay disclose a bone anchor that may range from 3-18mm, which converted is 0.118 inches to 0.708 inches (see Col. 3, lines 60-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the

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bone anchor of the combination of Goble et al. '692 and Kwan '197 having at least the dimensions as disclosed by Kay of a range of 0.118 to 0.708 inches to better fit the anchor into bone.

Claims 11, 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Goble et al. '692 and Kwan '197 and in further view of McCrory et al. (US Patent 6,333,971). The combination of Goble et al. '692 and Kwan '197 discloses the claimed invention except for a fiducial marker. McCrory et al. disclose a fiducial marker that may be anchored that allows for the device to be used with multiple imaging modalities such as CT, MRI, PET and SPECT to allow for the bone anchor to be viewed more easily by a surgeon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of over the combination of Goble et al. '692 and Kwan '197 having at least an fiduciary marker in view of McCrory et al. to better use the device in surgery.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Goble et al. '692 and Kwan '197. The combination of Goble et al. '692 and Kwan '197 disclose the claimed invention except for a driver insert being made of silicon. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the insert out of silicon, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Allowable Subject Matter

Claim 47 is allowed.

Response to Arguments

Applicant's arguments filed 1/23/2008 have been fully considered but they are not persuasive. With regards to the modification of Goble et al. and Kwan, Goble et al. teaches a bone anchor along with a driver for inserting it, as noted in the action above. With regards to the screw being self-drilling, the screw of Goble et al. is still considered to be "self-drilling" as the threads function to pull the screw into the bone area. As noted Goble et al. lacks the internal threads on the threaded protrusion recess. Goble et al. has a recess on the protrusion, but lacks the threads. Kwan discloses the threads, but doesn't show specifically what is designated to use them. However, Kwan teaches that a threaded male member is designed to use the threads to be connected to the implant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

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